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**Filed** : **October 20, 2003**

### **REMARKS**

The foregoing amendments are responsive to the January 30, 2007 Office Action. Applicant respectfully request reconsideration of the present application in view of the foregoing amendments and the following remarks.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

#### Response to Provisional Rejection of Claims 1-2, 8-12, 14, 17-20, 22, 25-27, 29-36 and 38-42 Under Obviousness-Type Double Patenting

The Examiner provisionally rejected Claims 1-2, 8-12, 14, 17-20, 22, 25-27, 29-36 and 38-42 on the ground of non-statutory obviousness-type double patenting over Claims 1-2, 5-9, 11, 17-18, 21-23 and 34-38 of copending Application No. 10/621,196.

Applicant has filed herewith a terminal disclaimer.

#### Response to Rejection of Claims 1, 3-8, 14, 16, 21 and 25-32 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 1, 3-8, 14, 16, 21 and 25-32 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. The combination of Blume with McEwan does not teach or suggest, inter alia, using radar data to compute a position of the distal end by identifying contrast between the distal end and body tissues, where the contrast results from the relative dielectric constants of the distal end and the body tissues.

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Regarding Claim 1, the cited combination does not teach or suggest a magnetic field source for generating a magnetic field, said magnetic field source outside the body, a radar system to measure radar data, a sensor system to measure positions of a plurality of fiduciary markers, a user input device for inputting commands to move said distal end, and a system controller for controlling a direction and amplitude of a magnetic field produced by controlling a plurality of currents in electromagnets of said magnetic field source in response to inputs from said user input device, said radar system, and said sensors said system controller configured to compute a location of said distal end by using said radar data to identify contrast between said distal end and body tissues, said contrast resulting from the relative dielectric constants of said distal end and the body tissues.

Regarding Claim 3, the cited combination does not teach or suggest the apparatus of Claim 1, the radar system including an impulse radar.

Regarding Claim 4, the cited combination does not teach or suggest the apparatus of Claim 1, the distal end including one or more magnets.

Regarding Claim 5, the cited combination does not teach or suggest the apparatus of Claim 1, where the system controller calculates a position error and controls the magnetic field source to move the distal end in a direction to reduce the position error.

Regarding Claim 6, the cited combination does not teach or suggest the apparatus of Claim 1, where the system controller integrates a position data of the distal end with a set of fiduciary markers.

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Regarding Claim 7, the cited combination does not teach or suggest the apparatus of Claim 1, where the system controller synchronizes a location of the distal end with a fluoroscopic image.

Regarding Claim 8, the cited combination does not teach or suggest the apparatus of Claim 1, further including an operator interface unit.

Regarding Claim 14, the cited combination does not teach or suggest the apparatus of Claim 1, further including an X-axis controller and amplifier, a Y-axis controller and amplifier, and a Z-axis controller and amplifier.

Regarding Claim 16, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the radar device includes a phased array.

Regarding Claim 21, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the radar system is configured to measure second harmonics produced by the distal end.

Applicant respectfully asserts that Claims 1, 3-8, 14, 16, and 21 are allowable over the prior art, and Applicant requests allowance of Claims 1, 3-8, 14, 16, and 21.

Response to Rejection of Claims 35, 37-38 and 43 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 35, 37-38 and 43 under 35 U.S.C. 103(a) as being unpatentable over Hastings (U.S. Patent No. 6,148,823) in view of Colley et al. (U.S. Patent No. 4,354,501), further in view of McEwan (U.S. Patent No. 6,914,552).

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Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second pluralities of poles. Colley teaches an ultrasonic catheter to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. The "C" magnet of Hastings produces a fixed magnetic field. The orientation of the field can be varied somewhat by moving the magnet (note that the field cannot practically be oriented in some directions as the patient's body would interfere with the magnet). Moreover, the field gradients produced by the magnet of Hastings do not provide substantially simultaneous control of orientation and elevation.

Regarding Claim 35, the cited combination does not teach or suggest an apparatus for controlling movement of a tool having a distal end to be inserted in a body, including, a magnetic field source configured in a cluster-like arrangement on a C-Arm forming a magnetic circuit and generating a magnetic field, the magnetic field source including a first plurality of electromagnet coils provided substantially above the body and a second plurality of electromagnet coils provided substantially below the body, a tool having a distal end responsive to the magnetic field, one or more piezoelectric rings disposed about the distal end, and a system controller for regulating electrical currents in the first plurality of electromagnet coils and the second plurality of electromagnet coils to produce a desired strength and orientation of the magnetic field to provide a position and command input to control the tool distal end position in orientation and elevation, and a radar system for measuring a position of the distal end.

Regarding Claim 37, the cited combination does not teach or suggest the apparatus of Claim 35, further including a radar system to locate the distal end.

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Regarding Claim 38, the cited combination does not teach or suggest the apparatus of Claim 35, wherein the system controller is configured to calculate respective torque and associated current for the magnetic source to configure the magnetic field to move the distal end to a desired location.

Applicant respectfully asserts that Claims 35, 37, 38 and 43 are allowable over the prior art, and Applicant requests allowance of Claims 35, 37, 38 and 43.

Response to Rejection of Claim 2 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 2 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552), further in view of Galel (U.S. Patent No. 5,492,131).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Galel teaches a servo system to control pushing/pulling on a proximal end of a catheter. The combination of Blume, McEwan and Galel does not teach or suggest, inter alia, a system controller for controlling a direction and amplitude of a magnetic field produced by controlling a plurality of currents in electromagnets of said magnetic field source in response to inputs from the user input device, the radar system, and the sensors.

Applicant respectfully asserts that Claim 2 is allowable over the prior art, and Applicant requests allowance of Claim 2.

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Response to Rejection of Claims 9-11 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 9-11 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552), further in view of Kawashima (U.S. Patent No. 4,292,961).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Kawashima teaches a system with sensors on the distal end of the catheter for controlling the position of the catheter within a blood vessel. The data provided by the sensor of Kawashima is perhaps sufficient to provide axial data within a blood vessel, but is insufficient to locate the longitudinal or other position aspects of the distal end within a cavity such as a heart chamber. Thus, the system of Kawashima does not teach or suggest, and does not provide sufficient information to allow a system controller to compensate for a dynamic position of a wall of a heart chamber.

Regarding Claim 9, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the system controller compensates for a dynamic position of a wall of a heart chamber, thereby offsetting a response of the distal end to the magnetic field such that the distal end moves in substantial unison with the wall.

Regarding Claim 10, the cited combination does not teach or suggest the apparatus of Claim 1, wherein a correction input is generated by an auxiliary device that provides correction data concerning a dynamic position of a wall of a heart chamber, and wherein the correction data are combined with measurement data from the radar system to offset a response of the control system so that the distal end moves substantially in unison with the wall.

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Regarding Claim 11, the cited combination does not teach or suggest the apparatus of Claim 10, wherein the auxiliary device includes at least one of an X-ray device, an ultrasound device, and a radar device.

Applicant respectfully asserts that Claims 9-11 are allowable over the prior art, and Applicant requests allowance of Claims 9-11.

Response to Rejection of Claims 12-13, 17, 20 and 34 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 12-13, 17, 20 and 34 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552), further in view of Blume '580 (U.S. Patent No. 6,014,580).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Blume '580 teaches a joystick or other device to provide inputs, including a "virtual catheter" to sense bending. Blume '580 does not teach or suggest the use of a virtual tip as described by Applicant. Moreover, Blume '580 does not teach or suggest a virtual tip with force feedback.

Regarding Claim 12, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the user input device includes a virtual tip control device to allow user control inputs.

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Regarding Claim 13, the cited combination does not teach or suggest the apparatus of Claim 1, further including: a virtual tip with force feedback.

Regarding Claim 17, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the system controller coordinates operation of an X-axis Controller, a Y-axis Controller, and a Z-axis Controller, and wherein the user input device includes a virtual tip.

Regarding Claim 20, the cited combination does not teach or suggest the apparatus of Claim 17, wherein the system controller causes the distal end to follow movements of the Virtual Tip.

Applicant respectfully asserts that Claims 12-13, 17, 20 and 34 are allowable over prior art, and Applicant requests allowance of Claims 12-13, 17, 20 and 34.

Response to Rejection of Claims 18-19, 22, 24 and 33 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 18-19, 22, 24 and 33 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552), further in view of Blume et al. (U.S. Patent No. 6,014,580), in even further view of Green (U.S. Patent No. 5,808,665).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Blume '580 does not teach or suggest tactile feedback. Green teaches tactile feedback based on pressure sensors at the end of a remotely-controlled instrument. In Green, the information for feedback is obtained by direct measurement, and Green requires specific sensors on the end of the surgery device dedicated to measuring



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feedback information. Green does not teach or suggest computing tactile feedback information according to a position error between a present position of the distal end of the tool and the desired position in a servo-feedback system.

Regarding Claim 18, the cited combination does not teach or suggest the apparatus of Claim 17, wherein the Virtual Tip provides tactile feedback to an operator.

Regarding Claim 19, the cited combination does not teach or suggest the apparatus of Claim 17, wherein the Virtual Tip provides tactile feedback to an operator according to a position error between an actual position of the distal end and a desired position of the distal end.

Regarding Claim 22, the cited combination does not teach or suggest the apparatus of Claim 1, further including a virtual tip controller, wherein the Virtual Tip Controller outputs a tactile feedback response control to a Virtual Tip.

Regarding Claim 24, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the system controller initiates a tactile feedback response by providing feedback data to the user input device.

Applicant respectfully asserts that Claims 18, 19, 22, and 24 are allowable over the prior art, and Applicant requests allowance of Claims 18, 19, 22, and 24.

Response to Rejection of Claim 36 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 36 under 35 U.S.C. 103(a) as being unpatentable over Hastings in view of Colley, further in view of McEwan, and further in view of Galel.

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Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second pluralities of poles. Colley teaches an ultrasonic catheter to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip. McEwan teaches low frequency (below 200 Hz) magnetic excitation in combination with a radar motion sensor. McEwan does not teach or suggest piezoelectric rings. Galel teaches controlling force at the proximal end the catheter, not the distal end.

Regarding Claim 36, the cited prior art does not teach or suggest an apparatus for magnetically controlling a medical tool having piezoelectric rings at its distal tip and being sensed by a radar system.

Applicant respectfully asserts that Claim 36 is allowable over the prior art, and Applicant requests allowance of Claim 36.

Response to Rejection of Claims 39-41 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 39-41 under 35 U.S.C. 103(a) as being unpatentable over Hastings as modified by Colley, McEwan and Galel, and further in view of Blume and Kawashima.

Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second pluralities of poles. Colley teaches an ultrasonic catheter to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Galel teaches controlling the proximal end of the catheter. In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location

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of the implant. Kawashima teaches a system with sensors on the distal end of the catheter for controlling the position of the catheter within the cavity (e.g., between the walls of a blood vessel). The data provided by the sensor of Kawashima is insufficient to locate the position of the distal end within the body or with respect to fiducial markers.

Regarding Claim 39, the cited combination does not teach or suggest the apparatus of Claim 36, wherein the system controller provides a closed servo loop circuit that corrects for movement of an organ in the body such that the distal end moves substantially unison with the organ.

Regarding Claim 40, the cited combination does not teach or suggest the apparatus of Claim 39, wherein data about movement of the organ is generated by an auxiliary device that provides dynamic data concerning the movement, and wherein when the dynamic data are combined with measured positions of a plurality of fiduciary markers that define a stereotactic frame.

Regarding Claim 41, the cited combination does not teach or suggest the apparatus of Claim 40, wherein the auxiliary device includes at least one of: a fluoroscopic imaging system, and ultrasonic imaging system, or a radar imaging system.

Applicant respectfully asserts that Claims 39-41 are allowable over the prior art, and Applicant requests allowance of Claims 39-41.

Response to Rejection of Claim 42 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 42 under 35 U.S.C. 103(a) as being unpatentable over Hastings in view of Colley, further in view of McEwan, and further in view of Blume.

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Hastings teaches mechanically manipulating a conventional "C" magnet having two poles. Hastings does not teach or suggest first and second pluralities of poles. Colley teaches an ultrasonic catheter to detect air emboli. Colley does not teach or suggest using ultrasonics to locate a catheter tip. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant.

Regarding Claim 42, the cited combination does not teach or suggest the apparatus of Claim 35, further including a Virtual Tip, wherein movement of at least a portion of the Virtual Tip causes said system controller to control the magnetic field source to move the distal end.

Applicant respectfully asserts that Claim 42 is allowable over the prior art, and Applicant requests allowance of Claim 42.

Response to Rejection of Claims 15 and 23 Under 35 U.S.C. 103(a)

The Examiner rejected Claims 15 and 23 under 35 U.S.C. 103(a) as being unpatentable over Blume et al. (U.S. Application No. 2001/0021805) in view of McEwan (U.S. Patent No. 6,914,552), further in view of Hunter et al. (U.S. Patent No. 6,381,485).

In Blume, a moveable magnet is mechanically manipulated to produce a desired field. Blume teaches sensors to sense one or more fiduciary markers but Blume does not teach or suggest sensors to sense the location of the implant. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Hunter does not teach or suggest these missing elements.

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Regarding Claim 15, the cited combination does not teach or suggest the apparatus of Claim 1, the sensor system including a 6-DOF sensor.

Regarding Claim 23, the cited combination does not teach or suggest the apparatus of Claim 1, wherein the system controller is configured to calculate a position error of the distal end of the catheter tip using at least in part data from the radar device and the 6-DOF sensor in order to control the magnetic field source to reduce the position error.

Applicant respectfully asserts that Claims 15 and 23 are allowable over the prior art, and Applicant requests allowance of Claims 15 and 23.

Response to Rejection of Claim 44 Under 35 U.S.C. 103(a)

The Examiner rejected Claim 44 under 35 U.S.C. 103(a) as being unpatentable over Hastings (U.S. Patent No. 6,148,823) in view of Colley et al. (U.S. Patent No. 4,354,501), further in view of McEwan (U.S. Patent No. 6,914,552), further in view of Hunter et al. (U.S. Patent No. 6,381,485).

As discussed above, Hastings does not teach or suggest electromagnets and Colley does not teach or suggest using ultrasonics to locate the distal end. McEwan teaches detecting a vibrating object using a radar motion sensor. The system of McEwan operates by sensing vibration, and cannot be used to sense an object that is not vibrating. Hunter does not teach or suggest these missing elements.

Regarding Claim 44, the cited combination does not teach or suggest the apparatus of claim 43, wherein the system controller uses at least position data from the radar system and fiducial marker position data from a 6-DOF sensor to compute a position of the distal end with respect to a stereotactic frame.

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Applicant respectfully asserts that Claim 44 are allowable over the prior art, and Applicant requests allowance of Claim 44.


**Summary**

Applicants respectfully assert that Claims 1-24 and 35-44 are in condition for allowance, and Applicants request allowance of Claims 1-24 and 35-44. If there are any remaining issues that can be resolved by a telephone conference, the Examiner is invited to call the undersigned attorney at (949) 721-6305 or at the number listed below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By:   
Lee W. Henderson Ph.D.  
Registration No. 41,830  
Attorney of Record  
Customer No. 20,995  
(949) 760-0404

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